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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,876	06/28/2000	Mercy M. Davidson	0575/56614/JPW/JML/HA	6365

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Cooper & Dunham LLP  
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EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/604,876

Applicant(s)

DAVIDSON, MERCY M.

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,9 and 12-19 is/are pending in the application.  
4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,9 and 12 is/are allowed.
- 6) ☐ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) 3-5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1635

### **DETAILED ACTION**

An amendment was received and entered on 5/24/04.

Claims 1, 3-5, 8, 9, and 12-19 remain pending in the application. Claims 13-19 were withdrawn from consideration in Paper No. 7 as being drawn to a non-elected invention. Applicant timely traversed the restriction requirement which was subsequently made final.

Claims 1, 3-5, 8, 9 and 12 are under consideration in this Office Action.

### ***Rejections Withdrawn***

The rejection of claims 3-5 under 35 USC 102 over Wang is withdrawn for the following reasons. First, with regard to claims 2 and 5, drawn to cell lines AC16 and RL 14, the Declaration of Mercy Davidson presented evidence that AC16 and RL14 are morphologically distinguishable from the W1 cells of Wang. This alone would have been sufficient to overcome the rejections of claims 2 and 5. However, the rejection of claims 3-5 was improper in its reliance on inherency of the expression of the markers beta-myosin heavy chain, connexin-43, and desmin and is withdrawn. Note that the rejection is maintained for claim 1, as discussed more fully below.

The rejection of claims 8, 9, and 12 under 35 USC 112, first paragraph is withdrawn in view of Applicant's amendments requiring expression of T antigen and one or more gene specifically expressed by the primary post-mitotic cells of step (a).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1635

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (In Vitro Cellular and Developmental Biology 27(1): 63-74, 1/1991).

Claim 1 is a product-by-process claim drawn to an immortalized human undifferentiated cardiomyocyte cell line. MPEP 2113 states that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by these steps. Claim 1 requires cell fusion between a post-mitotic primary non-immortalized human cardiomyocyte and a human fibroblast that has been treated with ethidium bromide, lacks mitochondrial DNA, and comprises a replicable vector expressing SV40 large T antigen. Thus the only clear structural requirements of the product are that it can contain no fibroblast mitochondrial DNA. The claim does not actually require that the SV40 large T antigen replicable vector must be in the final product. Wang teaches a human fetal cardiac myocyte cell line designated W1. This line is considered to be immortalized because it was maintained in culture for one year. See abstract. The cell line is considered to be undifferentiated because it is less differentiated than cultured fetal myocytes. See page 66, column 1, last paragraph. Wang teaches a human fetal cardiac myocyte cell line designated W1. This line is considered to be immortalized because it was maintained in culture for one year. See abstract. Furthermore, although it is not a requirement of the rejected claim, the W1 cells carry an expression construct encoding SV40 T antigen (pRSVTag). See page 67, column 2, last complete sentence. Finally, because the W1 line is recognized as a cardiomyocyte cell line, and because beta-myosin heavy chain, connexin-43, and desmin are recognized as cardiomyocyte markers, the W1 line is considered to inherently express these markers. The Office does not have the facilities for examining

Art Unit: 1635

and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989).

### ***Response to Arguments***

Applicant's arguments filed 5/24/04 have been fully considered but they are not persuasive. Applicant argues that the W1 cell line of Wang is not the same as the claimed cell line, relying for support on the Declaration of Mercy Davidson, which has been fully considered. Applicant argues that the cells of Wang have different morphological and growth characteristics than the claimed cells. This is unpersuasive because the claims are not limited by any particular morphological or growth characteristics, and Applicant has presented no evidence that these characteristics would necessarily flow from the claimed method steps.

***Conclusion***

Claims 8, 9, and 12 are allowable. Claims 3-5 are objected to as depending from a rejected claim, but would be allowable if rewritten in independent form incorporating all of the limitations of the parent claim.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



DAVE T. NGUYEN  
PRIMARY EXAMINER

Richard Schnizer, Ph.D.